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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/350,401	SETTE ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41 and 52-62* is/are pending in the application.

4a) Of the above claim(s) *54,56,59 and 60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,52,53,55,57,58,61,62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/08 has been entered.

2. Claims 41,52,53,55,57,58,61,62 are under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 52,55,57,58,61,62 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

1) There is no support in the specification as originally filed for the composition of claim 52. The specification discloses vaccines or pharmaceutical compositions containing a pharmaceutically acceptable carrier, but does not disclose then scope of claim 52 which encompasses other types of composition containing nonpharmaceutically acceptable carriers.

Regarding applicants comment, the cited passage of the specification refers to vaccines and carriers for vaccines that constitute pharmaceutical carriers. The specification does not disclose the scope of claim 52 which encompasses other types of compositions containing nonpharmaceutically acceptable carriers. Regarding applicants comments, "nonpharmaceutically acceptable carriers" means carriers that are not pharmaceutically acceptable (aka could not be used in humans or could not be used in

vivo). Regarding applicants comments about water and saline, the specification, page 43, first paragraph refers to water/saline for a vaccine which is administered in vivo. It does not disclose or encompass water/saline as per unsuitable for in vivo administration. Regarding applicants comments about carriers, all of the carriers referred to on page 43 are for vaccines. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

3. Patentability/Validity -- Specification -- Written description .(115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.. . ."), the specification must contain an equivalent description of the claimed subject matter. *A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.*

The MPEP section 2163.05 I. states:

Addition of Generic Claim

The written description requirement for a claimed genus may be satisfied through

sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus.
As per above, the specification does not disclose the scope of claim 52 which encompasses other types of compositions containing nonpharmaceutically acceptable carriers.

2) There is no support in the specification as originally filed for the recitation of "wherein said one or more second peptides is a cytotoxic T cell (CTL)- inducing peptide or a helper T cell (HTL)-inducing peptide" in claim 55. Regarding applicants comments, the aforementioned composition is not disclosed in the cited pages of the specification. There is no support in the specification as originally filed for the scope of the claimed inventions (e.g. the claimed inventions constitutes new matter).

Regarding applicants comments, whilst the cited passages disclose vaccine compositions containing the components under consideration, the instant claims encompass nonvaccine compositions containing the aforementioned ingredients that are not disclosed in the specification. Regarding applicants comments, the quoted passage of the specification from page 5 of the instant amendment states: "A polyepitopic peptide composition … **for the administration to individuals at risk for both HBV and HCV infection.**". Thus, the composition referred to in said passage is a vaccine.

3) There is no support in the specification as originally filed for the composition of claims 61,62. The specification discloses the peptide of claim 61/62 linked to a CTL epitope or contained in a vaccine composition, but does not disclose the claimed composition which is not a vaccine and wherein the peptides are not linked.
Regarding applicants comments, whilst the cited passages disclose vaccine compositions containing the components under consideration, the instant claims encompass nonvaccine compositions containing the aforementioned ingredients that are not disclosed in the specification. In addition, regarding the cited passage of page 84 of the specification, said passage refers to ""epitopes from the various disease associated sources" wherein the HTL peptides recited in the instant claims are not disease associated HTL. Regarding applicants comments, the quoted passage of the

specification from page 5 of the instant amendment states: “A polyepitopic peptide composition … **for the administration to individuals at risk for both HBV and HCV infection**.". Thus, the composition referred to in said passage is a vaccine.

5. Claim 61 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The claimed composition encompasses use of a “pan-DR-binding epitope” wherein said molecule is defined as per page 51, first paragraph of the specification. Said pan-DR-binding epitope encompasses any synthetic nonnaturally occurring peptide with the functional attributes as per said definition. Said paragraph of the specification discloses a single peptide with said attributes. The claims encompass a vast collection of artificial peptides with the functional attributes of a pan-DR-binding epitope wherein the identity of said peptides is not disclosed in the specification and it appears unpredictable as to what peptides would or would have said functional attributes.

The skilled artisan cannot envision the detailed structure of the encompassed antibodies and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at

1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

"The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the claimed composition encompasses use of a "pan-DR-binding epitope" wherein said molecule is defined as per page 51, first

paragraph of the specification. Said pan-DR-binding epitope encompasses any synthetic nonnaturally occurring peptide with the functional attributes as per said definition. Said paragraph of the specification discloses a single peptide with said attributes. The additional cited passage referred to by applicant discloses three additional examples. The claims encompass a vast collection of artificial peptides with the functional attributes of a pan-DR-binding epitope wherein the identity of said peptides is not disclosed in the specification and it appears unpredictable as to what peptides would or would have said functional attributes. The skilled artisan cannot envision the detailed structure of the encompassed antibodies and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997).

Regarding applicants comments about the state of the art, the MPEP section 716.01(c) [R-2] states:

>II. < ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

6. Claims 53 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed pharmaceutical composition. The specification does not disclose how to use the instant invention for the in vivo treatment/prevention of HBV in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment/prevention of HBV infection in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment/prevention of HBV infection in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same. . . .35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining

whether a disclosure would require undue experimentation. These factors were set forth as follows:
(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.
Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d
1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the claimed inventions are drawn to a pharmaceutical composition that can be used to treat/prevent HBV infection. The substantial/real life use for the claimed inventions are preventing and treating HBV infection in humans. There is currently no known pharmaceutical composition containing a single HBV peptide for treating or preventing HBV in humans. Basalp et al. teach that the currently used HBV vaccine contains intact HBV surface antigen (HBs, see column 1, page 2).
The claimed invention does not contain intact HBs and only contains a single peptide derived from HBV polymerase. There is no evidence of record that intact polymerase (or the pol derived peptide recited in the claim) can be used to treat HBV infection in humans. Basalp et al. teach that antibody responses against HBs that are produced by the HBV vaccine are an important component of the mechanism of action of the HBV vaccine (se page 1, column 1, continued on page 2 and pages 4-6). There is no evidence of record that the peptide recited in the claim can elicit a protective antibody response for the treatment of HBV infection. In addition, the peptide recited in the claims does not bind most HLA alleles and therefore would not even elicit CTL in most individuals.
Thus, the state of the art is that it is highly unpredictable whether the peptide recited in the claims could be used as a pharmaceutical composition to treat/prevent HBV infection in humans. As per Wands factor (8), the claimed inventions are used for preventing and treating HBV infection. Regarding Wands factors 1-3,7 there is no

disclosure in the specification of experimental data indicating that the claimed peptide can be used to prevent or treat HBV in vivo in humans. Thus, use of a particular peptide for treatment/prevention of HBV infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides no evidence predictive of whether the claimed invention could be used in vivo in humans to treat/prevent malarial infection. Regarding Wands factor 6, the relative skill of those in the art is high (e.g. Ph.D. or M.D.). Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

Regarding applicants comments, the claimed invention is drawn to a pharmaceutical composition wherein the intended use for said composition disclosed in the specification is the in vivo treatment of disease in humans. Regarding applicants comments about MPEP section 2164.01, "pharmaceutical composition" is an intended use (aka in vivo treatment of disease in humans). The claimed inventions are drawn to a pharmaceutical composition that can be used to treat/prevent HBV infection. The substantial/real life use for the claimed inventions are preventing and treating HBV infection in humans. There is currently no known pharmaceutical composition containing a single HBV peptide for treating or preventing HBV in humans. Basalp et al. teach that the currently used HBV vaccine contains intact HBV surface antigen (HBs, see column 1, page 2). The claimed invention does not contain intact HBs and only contains a single peptide derived from HBV polymerase. There is no evidence of record that intact polymerase (or the pol derived peptide recited in the claim) can be used to treat HBV infection in humans. Basalp et al. teach that antibody responses against HBs that are produced by the HBV vaccine are an important component of the mechanism of action of the HBV vaccine (se page 1, column 1, continued on page 2 and pages 4-6). There is no evidence of record that the peptide recited in the claim can elicit a protective antibody response for the treatment of HBV infection. In addition, the peptide recited in the claims does not bind most HLA alleles and therefore would not even elicit CTL in most individuals. Thus, the state of the art is that it is highly unpredictable whether the peptide recited in the claims could be used as a pharmaceutical composition to treat/prevent HBV infection in humans. As per Wands factor (8), the claimed inventions

are used for preventing and treating HBV infection. Regarding Wands factors 1-3,7 there is no disclosure in the specification of experimental data indicating that the claimed peptide can be used to prevent or treat HBV in vivo in humans. Thus, use of a particular peptide for treatment/prevention of HBV infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides no evidence predictive of whether the claimed invention could be used in vivo in humans to treat/prevent malarial infection.

7. In view of previously pending claim 45, claim 41 is interpreted as encompassing the peptide recited in the claim attached to another peptide(s). The T helper peptides (aka HTL) disclosed in the specification are larger than 5 amino acids (for example see claim 62). Thus, it appears that applicant intended that claim 41 encompass the peptide of claim 41 attached to other peptides and wherein the aggregate length of the peptide complex is greater than the 15 amino acids of the isolated peptide portion of the peptide complex. Regarding applicants comments, the interpretation of claim 41 merely refers to said claim as defined by previously pending claim 45. The Examiner has not "attached his own meaning" to said claim, he has simply interpreted said term in view of applicants definition of the claim in view of previously pending claim 45.

Regarding applicants comments, the MPEP section 2173.05(a) states:

III. TERMS USED CONTRARY TO THEIR ORDINARY MEANING MUST BE CLEARLY REDEFINED IN THE WRITTEN DESCRIPTION

*Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer**, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms.** See, e.g., Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can*

act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term."); Hormone Research Foundation Inc. v. Genentech Inc., 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant's use of the term. See Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202, 64 PATENTABILITY ***2173.05(b)*** *2100-215 Rev. 5, Aug. 2006 USPQ2d 1812, 1818 (Fed. Cir. 2002).*

The T helper peptides (aka HTL) disclosed in the specification are larger than 5 amino acids (for example see claim 62). Thus, it appears that applicant intended that claim 41 encompass the peptide of claim 41 attached to other peptides and wherein the aggregate length of the peptide complex is greater than the 15 amino acids of the isolated peptide portion of the peptide complex.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 41,52,53,55,57,58 stand rejected under 35 U.S.C. 102(e) as being anticipated by Seeger et al. (US Patent 5,360,714) as evidenced by Pasek et al.

Seeger et al. teach HBV pol protein wherein the peptide recited in the claims is found in HBV pol (see column 10, third paragraph, column 5, third paragraph, columns 11-12). The HBV pol protein contains multiple peptides (it is around 90kd) and the amino acids found in said molecule in addition to the peptide recited in the claims function as "linkers". The HBV molecule of 90kd would be expected to contain multiple T cell epitopes. The protein can be prepared in a buffer such as disclosed by Seeger et al., column 14, first complete paragraph wherein said buffer would be encompassed by A "pharmaceutically acceptable carrier". The art recognized that the peptide recited in the claims is found in HBV pol (see Pasek et al., Figure 2).

Regarding applicants comments, see section 6 of this Office Action.

10. No claim is allowed.

11. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Primary Examiner, Art Unit 1644